

## REMARKS/ARGUMENTS

### I. Status of claims

Claims 1, 9, 14, 16, and 21 are amended.

Claims 6-8, 15, and 22-25 are withdrawn.

Claims 1-5, 9-14, and 16-21 are pending.

### II. Amended claims 1, 9, 16 and 21 satisfy 35 U.S.C. §112, 2<sup>nd</sup> ¶ requirements.

Claims 1, 9, and 16 are amended so that the steps are consistent with the preamble of the claim as the examiner suggested. Claim 21 has been amended to reflect that an embryo is a plant material. Support for the claim amendments can be found throughout the specification, especially on paragraphs [00019], [00036], [00093], and [00099-96].

Claims 16-21 were rejected under 35 U.S.C. §112, 2<sup>nd</sup> ¶ requirements, because the Office Action alleges omission of essential steps. Claim 16 has been amended. Claim 16 and its dependent claims 17-21 satisfy the §112 second paragraph requirements.

### III. Amended claims 16-21 satisfy 35 U.S.C. §112, 1<sup>st</sup> ¶ requirements.

The present specification provides L-cysteine, an antioxidant, as an example and provides L-cysteine concentration ranges from about 100 mg/l to about 400 mg/l. Obregon et al (1999), cited by the examiner, merely describes rice transformation that involved the use of cysteine or ascorbic acid. Obregon did not involve use of a plant histone expressing transgenic plant to study the effects of an antioxidant. Testing for a suitable antioxidant at a suitable concentration does not require undue experimentation. The present specification also provides experimental data regarding transformation of a plant material, e.g., zygotic material including immature embryos. Other plant materials such as leaf and roots are also suitable. The following is a direct quote from the MPEP (2164.01(b)):

As long as the specification discloses **at least one method for making and using the claimed invention** that bears a reasonable correlation to the entire scope of the claim, then the enablement requirement of 35 U.S.C. 112 is satisfied. *In re Fisher*, 427 F.2d 833, 839, 166 USPQ 18, 24 (CCPA 1970). Failure to disclose other methods by which the claimed invention may be made does not

render a claim invalid under 35 U.S.C. 112. *Spectra-Physics, Inc. v. Coherent, Inc.*, 827 F.2d 1524, 1533, 3 USPQ2d 1737, 1743 (Fed. Cir.), cert. denied, 484 U.S. 954 (1987).

The examiner does not provide evidence to show that the claimed method would not work with other antioxidants. The law does not require the applicant to test and provide data for every conceivable antioxidant at all possible concentrations for all possible plant tissue material. Given the guidance and experimental results in the specification, routine experimentation to test for other suitable antioxidants is not undue experimentation.

The fact that some experimentation is necessary does not preclude enablement; what is required is that the amount of experimentation **"must not be unduly extensive."** *PPG Indus., Inc. v. Guardian Indus., Corp.*, 75 F.3d 1558, 1564 (Fed. Cir. 1996) (quoting *Atlas Powder Co. v. E.I. DuPont de Nemours & Co.*, 750 F.2d 1569, 1576 (Fed. Cir. 1984)).

That is not to say that the specification itself must necessarily describe how to make and use every possible variant of the claimed invention, for the artisan's knowledge of the prior art and **routine experimentation can often fill gaps, interpolate between embodiments, and perhaps even extrapolate beyond the disclosed embodiments**, .... *AK Steel Corp. v. Sollac*, 344 F.3d 1234, 1244 (Fed. Cir. 2003).

In *Wands* the court observed that **"the test is not merely quantitative, since a considerable amount of experimentation is permissible**, if it is merely routine, *In re Wands*, 858 F.2d 731, 737 (Fed. Cir. 1988).

The enablement requirement is met **if the description enables any mode of making and using the invention**. *Johns Hopkins Univ. v. Cellpro, Inc.*, 152 F.3d 1342, 1361 (Fed. Cir., 1998)

Applicants' disclosure that L-cysteine is suitable antioxidant at concentrations of about 100-400 mg/l for plant zygotic material enables the pending claims. Therefore, amended claims 16-21 satisfy 35 U.S.C. §112, 1<sup>st</sup> ¶ requirements.

**IV. Claims 14, 16, 18, and 20 are not obvious under 35 U.S.C §103(a) over Enriquez-Obregon et al., (1999) in view of Mysore et al. (2000).**

On page 7 of the Action, the examiner admits that Obregon et al. does teach step (a) of claim 16. Mysore et al., (2000) is a post-priority publication and therefore not a prior art. Nevertheless, Mysore et al., (2000) does not mention increase in transformation efficiency of host monocot plants. In addition, Obregon et al., (2000) teaches away from the present disclosure by stating that cysteine concentrations of 80 mg/l were “not suitable for regeneration” (p. 163, last paragraph). Obregon and Mysore can not be properly combined and the examiner has not established a *prima facie* case of obviousness.

**[T]here must be some suggestion, motivation, or teaching in the prior art** that would have led a person of ordinary skill in the art to select the references and combine them in the way that would produce the claimed invention. *Karsten Mfg. Corp. v. Cleveland Golf Co.*, 242 F.3d 1376, 1385, 58 USPQ 2d 1286, 1293 (Fed. Cir. 2001).

**A showing of a suggestion, teaching, or motivation to combine the prior art references is an essential component of an obviousness holding.** *Brown & Williamson Tobacco Corp. v. Philip Morris Inc.*, 229 F.3d 1120, 1124-25 (Fed. Cir. 2000).

Obviousness cannot be established by combining the teachings of the prior art to produce the claimed invention, absent some teaching or suggestion supporting the combination. **The best defense against hindsight-based obviousness analysis is the rigorous application of the requirement for a showing of a teaching or motivation to combine the prior art references.** Combining prior art references without evidence of such a suggestion, teaching, or motivation **simply takes the inventor's disclosure as a blueprint for piecing together the prior art to defeat patentability—the essence of hindsight.** Broad conclusory statements regarding the teaching of multiple references, standing alone, are not evidence. *Ecolochem, Inc. v. Southern Cal. Edison Co.*, 227 F.3d 1361 (Fed. Cir. 2000).

Even if Obregon and Mysore were combined, the combination still would not render the pending claims obvious because, none of the references, either alone or in combination teach all the limitations of the pending claims—monocot plants, increase in plant histone levels, antioxidant, and increase in transformation efficiency.

**V. Claim 21 is not obvious under 35 U.S.C §103(a) over Enriquez-Obregon et al., (1999) in view of Mysore et al. (2000) and Yu et al. (US 6,215,051).**

On page 8 of the Action, the examiner admits that Obregon and Mysore do not teach transforming embryo. As discussed herein on section IV above, Mysore is a post-priority reference and Obregon does not teach or suggest using a plant histone gene to increase transformation efficiency. Yu merely teach that rice embryo is used for rice transformation.

A rejection cannot be predicated on the mere identification of individual components of claimed limitations. Rather, particular findings must be made as to the reason the skilled artisan, **with no knowledge of the claimed invention, would have selected these components for combination in the manner claimed.** *In re Werner Kotzab*, 217 F.3d 1365, 1371, 55 U.S.P.Q.2D (BNA) 1313, 1317 (Fed. Cir. 2000).

Even if all the these publications were combined, the combination still would not meet all the limitations of claim 21, because, an increase in transformation efficiency (as opposed to mere transformation) was not shown for a monocot host plant that was transformed by *Agrobacterium* starting with a plant zygotic material.

Therefore, applicants request withdrawal of this rejection and allowance of the pending claims.

**VI. Claim 17 is not obvious under 35 U.S.C §103(a) over Enriquez-Obregon et al., (1999) in view of Mysore et al. (2000) and Narasimhulu et al. (1996).**

On page 9 of the Action, the examiner admits that Obregon and Mysore do not teach transforming a maize plant.

As discussed herein on section IV above, Mysore is a post-priority reference and Obregon does not teach or suggest using a plant histone gene to increase transformation efficiency. Narasimhulu merely discusses Gus gene transformation into maize genome. Even if these references were combined, the combination still would not render claim 17 obvious because, all the limitations of the pending claims—maize plant, increase in plant histone levels, antioxidant, and increase in transformation efficiency—are not taught.

Therefore, applicants request withdrawal of this rejection and allowance of the pending claims.

**VII. Double patenting rejections.**

If any of the pending claims are found allowable, applicants will file appropriate terminal disclaimers.

**VIII. Other issues.**

Applicants thank the examiner for considering claim Groups I and III and rejoining with the elected Group V on merits in this Action. Applicants have amended the specification to correct a typographical error. If there are any remaining issues, applicants request that the examiner call the applicants' representative to resolve any pending issue.

A one-month extension request is concurrently filed. No fees are believed due at this time, however, please charge any deficiencies or credit any overpayments to deposit account number 12-0913 with reference to our attorney docket number (3220-94790).

Respectfully submitted,

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